K052045

AUG 2 4 2005

7 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the PreMarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92.

1. Identification of Submitter:

Submitter:	Confirma, Inc.
Address:	821 Kirkland Avenue
	Kirkland, WA 98033
Phone:	425-576-1226
Fax:	425-576-9295
Contact:	Patricia A. Milbank
Title:	Regulatory Consultant
Phone:	425-894-9733
Fax:	425-865-9023
Date Prepared:	July 25, 2005

2. Identification of Product:

Trade Name:	Access Breast Coil
Regulatory Number:	21 CFR 892.1000
Regulation Name:	Magnetic Resonance Diagnostic Device
Common Name:	Coil, Magnetic Resonance Specialty
Regulatory Class:	Class II
Product Code:	90 MOS
Manufacturer:	Confirma, Inc.
	821 Kirkland Avenue
	Kirkland, WA 98033

4. Indications for Use

The Access Breast Coil is a 7-channel, phased array, receive-only RF coil, used in conjunction with a magnetic resonance scanner to produce diagnostic and interventional images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician. The device is designed to aid the physician in MR-guided breast biopsy, localization of lesions, and interventional procedures, providing lateral, medial and cranial-caudal access to the breast.

5. Device Description:

Access is a 7-channel, phased array breast coil optimized for parallel imaging of the chest wall, breast and axillary tissue. Access is a dual purpose coil, offering both diagnostic imaging and flexibility in interventional access. The coil's open design allows for flexibility in performing interventional procedures with lateral, medial and cranial-caudal access.

The design of the Access breast coil focuses on patient ergonomics, allowing for enhanced comfort during both diagnostic and interventional exams. Positioning accessories, including a headrest, armrest and torso pad, help to relieve pressure on the sternum and provide customized patient positioning during the acquisition of breast MRI studies and interventional procedures.

The coil consists of a supporting base and two insulating coil chambers, one for each breast. Each of the hollow coil chambers houses two coil elements that are insulated from the patient by a rigid plastic housing. The coil housing is made of plastic materials, which are fire rated and have high impact and tensile strength.

The bilateral, open breast coil design offers optimized imaging capabilities and maximum access to aid the physician in MR-guided breast biopsy, localization of lesions, and interventional procedures, providing lateral, medial and cranial-caudal access to the breast.

Features of the Access Breast Coil:

Imaging

- 7-channel phased array design uses multiple elements that surround the breast tissue
- Optimized for parallel imaging applications
- Supports both unilateral and bilateral imaging exams
- Compatible with Siemens 1.5T MRI systems
- 40 cm field of view
- Extensive coverage of chest wall and axilla
- High SNR

Ergonomics

- Large apertures to accommodate a major percentage of patient population
- Ergonomically designed for patient comfort to minimize motion artifact

- Positioning accessories include a flexible, adjustable headrest, arm rest and torso pad
- Cushioned head rest with mirror to reduce patient claustrophobic response
- Padded arm rests for increased patient comfort

Interventional Access

- Coil design allows lateral, medial and cranial-caudal interventional access
- Lighting is integrated into the coil for interventional procedures that demand a well lit area
- Compatible with SureLoc software to support interventional MRI

6. Comparison with Legally Marketed Devices

The Access Breast Coil is substantially equivalent to the legally marketed devices listed below:

Model:	Liberty 9000 Breast Coil
Manufacturer:	USA Instruments, Inc.
510 (k) Number:	K000993

Model:	Machnet Bilateral Open Breast Coil
Manufacturer:	Machnet BV
510 (k) Number:	K013985

Model:	Biopsy Breast Coil BBC-127
Manufacturer:	MRI Devices Corporation
510 (k) Number:	K041481

All of these breast coils are designed as receive-only RF coils and intended for use in conjunction with a magnetic resonance scanner to produce diagnostic images of the breast, chest wall and axillary tissues that can be interpreted by a physician.

The predicate devices are designed for use with various MR scanners. The Access Breast Coil is designed for use with the Siemens 1.5T MR scanner, as is the predicate device marketed by MRI Devices.

The Access Breast Coil is a 7-channel, phased array coil that allows bilateral and unilateral imaging of the breast. All of these breast coils have an open coil design to optimize imaging of breasts of various sizes.

The predicate devices allow lateral and medial access to the breast for biopsy and interventional procedures, while the Access Breast Coil is designed to allow for lateral, medial and cranial-caudal access to the breast.

7. Conclusions

The Access Breast Coil is substantially equivalent to the identified legally marketed devices. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. The Access Breast Coil provides images comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2005

Ms. Patricia A. Milbank
Regulatory Consultant
Confirma, Inc.
821 Kirkland Avenue, Suite100
KIRKLAND WA 98033

Re: K052045
Trade/Device Name: Access Breast Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 27, 2005
Received: July 28, 2005

Dear Ms. Milbank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K052045

6 Indication(s) for Use Statement

510(k) Number: To be assigned by FDA

Device Name: Access Breast Coil

Indications for Use:

The Access Breast Coil is a 7-channel, phased array, receive-only RF coil, used in conjunction with a magnetic resonance scanner to produce diagnostic and interventional images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician. The device is designed to aid the physician in MR-guided breast biopsy, localization of lesions, and interventional procedures, providing lateral, medial and cranial-caudal access to the breast.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052045